FEB - 6 2012

510(k) Summary of Safety and Effectiveness

This summary of 510k safety and effectiveness is being submitted in according with 21CFR part 807.92

Submitter: Edan Instruments, Inc
3/F - B, Nanshan Medical
Equipments Park, Nanhai Rd 1019#,
shekou, Nanshan Shenzhen,
518067 P.R. China
Tel: 86-755-26882220
Fax:86-755-26882223
Contact person: Randy Jiang

Date of Preparation: 2011-12-09

Proprietary Name: Patient Monitor Models iM8,iM8A, iM8B

Classification:

Description	Classification	Product code
21 CFR 870.1025 Arrhythmia detector and alarm (Including ST-segment measurement and alarm)	II	MHX
21 CFR 870.2300 Cardiac monitor (including cardiotachoment and rate alarm)	II	DRT
21 CFR 870.1130 Non-Invasive blood pressure measurement System	II	DXN
21 CFR 870.1110 Blood pressure computer	II	DSK
21 CFR 880.2910 Clinical Electronic Thermometers-Temperature Monitor with Probe	II	FLL
21 CFR 870.2700 Oximeter, Pulse	II	DQA
21 CFR 870.1400 Carbon Dioxide Gas Analyzer	II	CCK
21 CFR 868.2900 cable, transducer and electrode, patient, (including connector)	II	DSA
21 CFR 870.1025 Detector and Alarm, Arrhythmia	II	DSI

Regulatory Class: Class II

Legally Marketed Predicate Devices

Manufacturer	Predicate Device	510(k) number	Cleared date
Philips Medical System	MP5	K100939	April.1.2010
Edan Instruments, Inc	M3 and M3A	K102835	Dec.27.2010
Edan Instruments, Inc	M3B	K083821	May.14.2009

Device Description:

iM8 Series Patient Monitor can perform long-time continuous monitoring of multiple physiological parameters. Also, it is capable of storing, displaying, analyzing and controlling measurements, and it will indicate alarms in case of abnormity so that doctors and nurses can deal with them in time. The patient monitor supports software upgrade online and networking and build-in battery power is available for all the models.

iM8 Series Patient Monitor can monitor physiological parameters including SpO2, NIBP, ECG, RESP, TEMP, CO2, IBP. The above is the maximum configuration, the user may select different monitoring parameters in according with the requirement.

iM8 Series patient monitor includes three models iM8, iM8A, iM8B, from the view of the below table, screen size is the primary difference for three models.

Product models	Size (L×W×H)	Screen size	Monitoring features
iM8	320mm×150mm×265mm	12.1-inch	ECG/RESP, SpO_2, NIBP, TEMP, IBP,CO2
iM8A		10.4-inch	
iM8B		10.1-inch Width_screen	

Comparison with predicate device

The iM8 Series Patient Monitors have the following similarities to that which previously received 510(k) concurrence:

- have the same indications for use,
- use the similar operating principle,
- have the same or similar performance specifications

In summary, the iM8 Series Patient Monitor described in this submission is, in our opinion, substantially equivalent to the predicate device

Intended Use:

The monitor monitors parameters such as ECG (3-lead or 5-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO2), Invasive or non-invasive blood pressure (dual-IBP, NIBP), Temperature (dual-TEMP), Expired CO2.
The monitor is intended to be used only under regular supervision of clinical personnel. It is applicable to adult, pediatric, and neonatal usage in a hospital environment and during patient transport inside a healthcare facility.

The monitor is equipped with alarms that indicate system faults (such as loose or

defective electrodes), physiologic parameters that have exceeded the limits set by the operator, or both.

Contraindications: It is not intended for use in patient's home or residence, or when it has not been ordered by a physician.

Test Summary: The following quality assurance measures were applied to the development of the Patient Monitor

- Software testing
- Hardware testing
- Safety testing
- Environment test
- Risk analysis
- Final validation

Conclusion: Verification and validation testing was done on the Patient Monitor. This premarket notification submission demonstrates that Patient Monitor is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Edan Instruments, Inc.
c/o Mr. Randy Jiang
Certification Engineer
3/F-B, Nanshan Medical Equipment Park,
Nanhai Rd., 1019 No.
Shenzhen
CHINA 518067

FEB - 6 2012

Re: K113653
Trade/Device Name: Patient Monitor, Models iM8, iM8A, and iM8B
Regulation Number: 21 CFR 870.1025
Regulation Name: Patient Physiological Monitor (with arrhythmia detection or alarms)
Regulatory Class: Class II (two)
Product Codes: MHX, DXN, DRT, DSK, FLL, DQA, DSA, and DSI
Dated: November 12, 2011
Received: December 12, 2011

Dear Mr. Jiang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K113653

Device Name: Patient Monitor Models iM8 , iM8A, iM8B

The monitor monitors parameters such as ECG (3-lead or 5-lead selectable), Respiration (RESP), Functional arterial oxygen saturation (SpO2), Invasive or noninvasive blood pressure (dual-IBP, NIBP), Temperature (dual-TEMP), Expired CO2.
The monitor is intended to be used only under regular supervision of clinical personnel. It is applicable to adult, pediatric, and neonatal usage in a hospital environment and during patient transport inside a healthcare facility.

The monitor is equipped with alarms that indicate system faults (such as loose or defective electrodes), physiologic parameters that have exceeded the limits set by the operator, or both.

Prescription Use ___x___ And/Or Over the Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K113653